



Attorney Docket No. 17882-705

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of	)	PATENT APPLICATION
	)	
Richard Wisniewski et al.	)	Group Art Unit: 3743
	)	
Application No.: 08/895,782	)	Examiner: Ford
	)	
Filed: July 17, 1997	)	
	)	
Title: FREEZING AND THAWING	)	
VESSEL WITH THERMAL BRIDGE	)	
FORMED BETWEEN CONTAINER	)	
AND HEAT EXCHANGER	)	DATE: October 8, 1999

**DECLARATION UNDER 37 C.F.R. § 1.132**

I, David A. Vetterlein, declare as follows:

1. I received a Ph.D. in Biochemistry from the University of California at Santa Barbara in 1977. I am currently the Director for Process Development and Manufacturing for ICOS Corporation, where I lead a department of 28 people that is responsible for clinical and market manufacturing of biological products and for process development.

2. Prior to my current position, I have been a Senior Scientist in the Recovery Process Research and Development group at Genentech, Inc., where I was involved in various aspects of product and process research for development of various biopharmaceuticals. In total, I have over 22 years of experience in various aspects of biotechnology, biopharmaceuticals, and general pharmaceutical development.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

By: David A. Vetterlein  
David A. Vetterlein

Date: Oct. 6, 1999  
October 6, 1999

Country of Citizenship: U.S.A.

Residence: 9620 146<sup>th</sup> Place SE, Snohomish, WA 98296

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3. I am not a paid consultant, employee, or agent of the assignee of this patent application. I am not receiving compensation in exchange for providing this testimony.

5. I have read and understood U.S. Patent Nos. 5,609,035 to Cothorn et al. ("Cothorn"); 5,524,706 to Nakamura et al. ("Nakamura"); and 1,874,578 to Morrison ("Morrison").

6. I understand that, during the prosecution of the present invention, an issue has arisen regarding the definition of the term "biopharmaceutical product."

7. It is my opinion that an accurate and clear definition of biopharmaceutical product is: **a product derived from biological sources that has an intended therapeutic application and whose manufacturing is or will be regulated by pharmaceutical or veterinary regulatory agencies.**

8. It is my opinion that the Cothorn, Nakamura, and Morrison references do not suggest nor teach biopharmaceutical products, or devices or methods useful in processing biopharmaceutical products. In particular, it is my opinion that conventional milk, as disclosed in the Morrison reference, or conventional orange juice, as disclosed in the Cothorn reference, are not biopharmaceutical products.